

Claims

We claim:

- 1 1. A method of determining patient compliance in taking a medication, comprising
2 providing to the patient a combination of a medication and a detectable marker, the
3 combination to be taken by the patient as a result of the patient's own actions,
4 obtaining a sample of the patient's gaseous exhaled breath; and
5 analyzing the sample of the patient's breath to confirm the presence or absence of said
6 marker in the patient's breath as an indication of patient compliance or non-compliance in
7 taking the medication; wherein the medication is to be taken by volitional patient action at
8 specified times.

- 1 2. The method of claim 1 wherein the medication itself comprises said detectable
2 marker.

- 1 3. The method of claim 1 wherein the marker is an odorous substance.

- 1 4. The method of claim 3 wherein the sample of the patient's breath is analyzed to
2 confirm the presence of said marker by sensor technology selected from semiconductor gas
3 sensor technology, conductive polymer gas sensor technology, or surface acoustic wave gas
4 sensor technology.

- 1 5. The method of claim 4 wherein the sensor technology produces a unique electronic
2 fingerprint to characterize the marker such that the presence and concentration of the marker
3 is determined.

- 1 6. The method of claim 1 wherein the marker is a flavor ingredient selected from
2 trans-Anethole (1-methoxy-4-propenyl benzene) - anise; Benzaldehyde (benzoic aldehyde)

3 - bitter almond; Butyl isobutyrate (n-butyl 2, methyl propanoate) - pineapple;
4 Cinnamaldehyde (3-phenylpropenal) - cinnamon; Citral (2-trans-3, 7-dimethyl-2,
5 6-octadiene-1-al) - citrus; Menthol (1-methyl-4-isopropylcyclohexane-3-ol) - menthol; and
6 alpha-Pinene (2, 6, 6-trimethylbicyclo-(3,1,1)-2-heptene) - pine.

1 7. The method of claim 1 wherein the sample of the patient's breath is analyzed to
2 confirm the presence of said marker by a spectrophotometer.

1 8. The method of claim 1 wherein the sample of the patient's breath is analyzed to
2 confirm the presence of said marker by mass spectrometer.

1 9. The method of claim 1 wherein the marker is an additive combined with the
2 medication.

1 10. The method of claim 1 wherein the marker is a coating on the medication.

1 11. The method of claim 10 wherein a substance to stimulate salivation is included
2 with the marker.

1 12. The method of claim 1 wherein the marker is included with a liquid medication.

1 13. The method of claim 1 wherein the marker is included with a pulmonary
2 delivered medication.

1 14. The method of claim 1 wherein the marker is included with an intranasal
2 delivered medication.

1 15. The method of claim 1 wherein the marker is included with intravenously
2 delivered medication.

1 16. The method of claim 1 further comprising the step of recording data resulting
2 from analysis of the sample of the patient's breath.

1 17. The method of claim 1 further comprising the step of transmitting data resulting
2 from the analysis of the sample of the patient's breath.

1 18. The method of claim 1 where the analysis of the sample of the patient's breath
2 includes comparing the marker sensed in the sample of the patient's breath with a
3 predetermined signature profile of a specific marker.

1 19. The method of claim 18 wherein the predetermined signature profile of a specific
2 marker is associated with a specific drug.

1 20. The method of claim 18 wherein the predetermined signature profile of a specific
2 marker is associated with a class of drugs.

1 21. The method of claim 1 further comprising the step of capturing the sample of the
2 patient's breath in a vessel prior to analysis.

1 22. The method of claim 1 further comprising the step of dehumidifying the sample
2 of the patient's breath prior to analysis.

1 23. The method of claim 1 wherein the marker first reacts with enzymes in the
2 patient's mouth to be detectable.

1 24. The method of claim 1 wherein the marker first reacts with acids in the patient's
2 stomach to be detectable.

1 25. The method of claim 1 wherein the marker is absorbed in the patient's
2 gastrointestinal tract and excreted in the lungs.

1 26. The method of claim 1 wherein the data resulting from analysis of the sample of
2 the patient's breath includes marker concentration and, thus, medication concentration.

1 27. The method of claim 1 further comprising the step of identifying a baseline
2 marker spectrum for the patient prior to the patient's taking of the medication.

1 28. The method of claim 1 wherein said analysis further includes detecting exhalation
2 of the patient's breath with a sensor.

1 29. A method of producing medication which is detectable as an indication of patient
2 compliance in taking the medication comprising the steps of:

3 identifying a marker substance detectable in gaseous exhaled breath, and
4 producing a medication combined with said detectable marker substance, said
5 medication to be taken by volitional patient action at specified times whereby subsequent
6 analysis of the patient's breath will confirm the presence of said marker substance and thus
7 the patient's compliance in taking said medication.

1 30. The method of claim 1 wherein the marker is included with transdermally
2 delivered medication.